

WHAT IS CLAIMED IS:

1. A method of inhibiting the growth of a papillomavirus-transformed cell in a hyperplastic lesion in a subject comprising topically administering to said lesion a growth
5 inhibiting amount of a composition comprising (a) an expression cassette comprising a promoter, active in cells of said lesion, operably linked to a polynucleotide encoding a *p53* polypeptide, and (b) a pharmaceutical preparation suitable for topical delivery, wherein expression of said *p53* polypeptide inhibits growth of said cell.
- 10 2. The method of claim 1, wherein said subject is a mammal.
3. The method of claim 2, wherein said mammal is a human.
4. The method of claim 1, wherein said cell is a keratinocyte.
- 15 5. The method of claim 1, wherein said cell is an epithelial cell.
6. The method of claim 1, wherein said cell is a skin cell.
- 20 7. The method of claim 1, wherein said cell is a mucosal cell.
8. The method of claim 1, wherein said papillomavirus is a human papillomavirus.
9. The method of claim 1, wherein said lesion is selected from the group consisting
25 of a squamous cell hyperplastic lesion, premalignant epithelial lesion, psoriatic lesion, cutaneous wart, periungual wart, anogenital wart, epidermodysplasia verruciformis, an intraepithelial neoplastic lesion, focal epithelial hyperplasia, conjunctival papilloma, conjunctival carcinoma, or squamous carcinoma lesion.
- 30 10. The method of claim 1, wherein said expression cassette is carried in a viral vector.

11. The method of claim 10, wherein said viral vector is an adenoviral vector, a retroviral vector, an adeno-associated viral vector, a vaccinia viral vector or a pox viral vector.

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12. The method of claim 10, wherein said viral vector is an adenoviral vector.

13. The method of claim 1, wherein said expression cassette is carried in a nonviral vector.

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14. The method of claim 13, wherein said non-viral vector is a lipid.

15. The method of claim 1, wherein said composition is formulated as a mouthwash or mouthrinse.

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16. The method of claim 15, wherein said mouthwash further comprises a flavorant.

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17. The method of claim 16, wherein said flavorant is selected from the group comprising one or more flavor components selected from wintergreen oil, oregano oil, bay leaf oil, peppermint oil, spearmint oil, clove oil, sage oil, sassafras oil, lemon oil, orange oil, anise oil, benzaldehyde, bitter almond oil, camphor, cedar leaf oil, marjoram oil, citronella oil, lavender oil, mustard oil, pine oil, pine needle oil, rosemary oil, thyme oil, cinnamon leaf oil, and mixtures thereof.

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18. The method of claim 1, wherein said composition is formulated as a douche solution.

19. The method of claim 1, wherein said composition is formulated as an ointment or salve.

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20. The method of claim 1, wherein said composition is formulated as a cream for topical, anal or vaginal delivery.
- 5 21. The method of claim 1, wherein said composition is formulated as a spray or aerosol.
22. The method of claim 1, wherein said composition is formulated as a suppository for anal or vaginal delivery.
- 10 23. The method of claim 1, wherein the promoter is a constitutive promoter, an inducible promoter or a tissue specific promoter.
24. The method of claim 1, wherein inhibiting growth comprises in slowing or halting the growth of said lesion.
- 15 25. The method of claim 1, wherein inhibiting growth comprises a reduction in the size of said lesion.
26. The method of claim 1, wherein inhibiting growth comprises induction of apoptosis said cells of said lesion.
- 20 27. The method of claim 1, wherein inhibiting growth comprises induction of an immune response against said cells of said lesion.
- 25 28. The method of claim 1, further comprising subjecting said subject to a secondary anti-hyperplastic therapy.
29. The method of claim 28, wherein said secondary anti-hyperplastic therapy is chemotherapy, radiotherapy, immunotherapy, phototherapy, cryotherapy, toxin therapy, hormonal therapy or surgery.
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30. A mouthwash for inhibiting the growth of a papillomavirus-transformed cell in a hyperplastic lesion in a subject comprising (a) an expression cassette comprising a promoter operably linked to a polynucleotide encoding a *p53* polypeptide, and (b) a liquid carrier formulated for oral delivery.
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31. The mouthwash of claim 30, further comprising a flavorant.
32. The mouthwash of claim 31, wherein said flavorant is selected from the group comprising one or more flavor components selected from wintergreen oil, oregano oil,
10 bay leaf oil, peppermint oil, spearmint oil, clove oil, sage oil, sassafras oil, lemon oil, orange oil, anise oil, benzaldehyde, bitter almond oil, camphor, cedar leaf oil, marjoram oil, citronella oil, lavender oil, mustard oil, pine oil, pine needle oil, rosemary oil, thyme oil, cinnamon leaf oil, and mixtures thereof.
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33. A douche solution for inhibiting the growth of a papillomavirus-transformed cell in a hyperplastic lesion in a subject comprising (a) an expression cassette comprising a promoter operably linked to a polynucleotide encoding a *p53* polypeptide, and (b) a liquid carrier formulated for vaginal delivery.
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34. A suppository for inhibiting the growth of a papillomavirus-transformed cell in a hyperplastic lesion in a subject containing (a) an expression cassette comprising a promoter operably linked to a polynucleotide encoding a *p53* polypeptide, and (b) formulated for anal or vaginal delivery.
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35. A cream for inhibiting the growth of a papillomavirus-transformed cell in a hyperplastic lesion in a subject containing (a) an expression cassette comprising a promoter operably linked to a polynucleotide encoding a *p53* polypeptide, and (b) formulated for topical, anal or vaginal delivery.
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36. A solution for inhibiting the growth of a papillomavirus-transformed cell in a hyperplastic lesion in a subject containing (a) an expression cassette comprising a

promoter operably linked to a polynucleotide encoding a *p53* polypeptide, and (b) formulated for hypospray.

5 37. An aerosolized suspension for inhibiting the growth of a papillomavirus-transformed cell in a hyperplastic lesion in a subject containing an expression cassette comprising a promoter operably linked to a polynucleotide encoding a *p53* polypeptide.

10 38. A method of suppressing or preventing papillomavirus-mediated transformation of a cell in a subject comprising administering to said cell a composition comprising (a) an expression cassette comprising a promoter, active in said cell operably linked to a polynucleotide encoding a *p53* polypeptide, and (b) a pharmaceutical preparation suitable for topical delivery, wherein expression of said *p53* suppresses said transformation.

15 39. The method of claim 38, wherein said cell is a keratinocyte.

40. The method of claim 38, wherein said subject is a human.

20 41. The method of claim 38, wherein said subject is a human at risk of developing an oral hyperplastic lesion.

42. The method of claim 41, wherein said human at risk of developing an oral hyperplastic lesion is a human with a history of a previous oral hyperplastic lesion.

25 43. The method of claim 42, wherein said previous oral hyperplastic lesion is comprised of cells selected from the group consisting of premalignant epithelial cells, squamous intraepithelial neoplastic cells, squamous hyperplastic cells, and squamous cell carcinoma cells.

30 44. The method of claim 41, wherein said oral hyperplastic lesion is comprised of cells transformed by a papillomavirus.

45. The method of claim 44, wherein said papillomavirus is a human papillomavirus.
46. The method of claim 38, wherein said expression cassette is carried in a viral vector.
- 5 47. The method of claim 46, wherein said viral vector is an adenoviral vector, a retroviral vector, an adeno-associated viral vector, a vaccinia viral vector or a pox viral vector.
- 10 48. The method of claim 46, wherein said viral vector is an adenoviral vector.
49. The method of claim 38, wherein said expression cassette is carried in a nonviral vector.
- 15 50. The method of claim 49, wherein said nonviral vector is a lipid.
51. The method of claim 38, wherein said composition is formulated as a mouthwash or mouth rinse.
- 20 52. The mouthwash of claim 51, further comprising a flavorant.
53. The mouthwash of of claim 52, wherein said flavorant is selected from the group comprising one or more flavor components selected from wintergreen oil, oregano oil, bay leaf oil, peppermint oil, spearmint oil, clove oil, sage oil, sassafras oil, lemon oil, orange oil, anise oil, benzaldehyde, bitter almond oil, camphor, cedar leaf oil, marjoram oil, citronella oil, lavender oil, mustard oil, pine oil, pine needle oil, rosemary oil, thyme oil, cinnamon leaf oil, and mixtures thereof.
- 25 54. The method of claim 38, wherein said composition is formulated as a douche solution for vaginal delivery.
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55. The method of claim 38, wherein said composition is formulated as a suppository for anal or vaginal delivery.

5 56. The method of claim 38, wherein said composition is formulated as an ointment or salve.

57. The method of claim 38, wherein said composition is formulated as a cream for topical, anal or vaginal delivery.

10 58. The method of claim 38, wherein said composition is formulated as a spray or aerosol.

59. The method of claim 38, wherein said composition is formulated as a pill or capsule.

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60. The method of claim 38, wherein said composition is formulated for timed-release.